

Appln. No. 09/241,595
Amd. dated November 5, 2003
Reply to Office Action of May 6, 2003

Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (Currently amended). A method of stimulating or enhancing a CTL response to ~~an antigenic~~ a biologically active molecule in a mammalian subject, comprising administering to said subject by injection into the body of said subject an effective amount of a composition comprising ~~an antigenic~~ a biologically active molecule either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, wherein said ~~antigenic~~ biologically active molecule is not covalently modified or covalently attached to said HBsAg particle.

Claim 2 (Cancelled).

3 (Currently amended). The method of claim 1, wherein said CTL response is enhanced relative to that produced by the ~~antigenic~~ biologically active molecule alone.

4 (Currently amended). The method of claim 1, wherein said ~~antigenic~~ biologically active molecule, when administered

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without said HBsAg particle, is substantially ineffective in producing a CTL response in said subject.

5(Original). The method of claim 1, wherein said HBsAg particle is a recombinant HBsAg particle derived from a mammalian cell.

6(Currently amended). The method of claim 1, wherein said ~~antigenic~~ biologically active molecule is an antigenic protein or peptide.

7(Currently amended). The method of claim ~~10~~ 6, wherein said antigenic molecule is HIVenv/V3 peptide.

8(Previously presented). The method of claim 1, wherein said composition further comprises an immunostimulating molecule entrapped within or exposed or present at the surface of said HBsAg particle.

9(Previously presented). The method of claim 8, wherein said immunostimulating molecule is a cytokine.

10(Previously presented). The method of claim 8, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

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11 (Currently amended). A method of stimulating or modulating a CTL response to HBsAg in a mammalian subject, comprising administering to said subject by injection into the body of said subject an effective amount of a composition comprising an immunostimulating molecule either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, wherein said immunostimulating molecule is not covalently modified or covalently attached to said HBsAg particle.

Claim 12 (Cancelled).

13 (Previously presented). The method of claim 11, wherein said subject is a nonresponder at the CTL level when administered HBsAg particles without said immunostimulating molecule.

14 (Original). The method of claim 11, wherein said immunostimulating molecule is a cytokine.

15 (Original). The method of claim 11, wherein said immunostimulating molecule is cholera toxin (CT) protein or staphylococcal enterotoxin B (SEB) protein.

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16(Previously presented). The method of claim 11, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

17(Currently amended). A composition comprising an HBsAg particle and a biologically active molecule either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, wherein said biologically active molecule is not covalently modified or covalently attached to said HBsAg particle.

18(Original). The composition of claim 17, wherein said molecule is an antigen.

19(Original). The composition of claim 18, wherein said molecule is HIVenv/K^d peptide.

20(Previously presented). The composition of claim 17, further comprising an immunostimulating molecule either entrapped within the interior of said HBsAg particle or exposed or present at the surface of said HBsAg particle.

21(Original). The composition of claim 17, wherein said biologically active molecule is an immunostimulating molecule.

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22(Original). The composition of claim 21, wherein said immunostimulating molecule is a cytokine.

23(Original). The composition of claim 21, wherein said immunostimulating molecule is an immunostimulatory oligonucleotide.

24(Original). The composition of claim 21, wherein said immunostimulating molecule is cholera toxin (CT) protein or staphylococcal enterotoxin B (SEB) protein.

25(Original). The composition of claim 17, further comprising a glycolipid incorporated into the exterior surface of the lipid bilayer of said HBsAg particle.

26(Original). The composition of claim 17, wherein said composition is prepared by incubating said particle in an aqueous medium in the presence of said molecule.

27(Original). A method of incorporating a biologically active molecule into an HBsAg particle, comprising incubating said particle in an aqueous medium in the presence of said molecule.

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28 (Currently amended). The method of claim 27, wherein the temperature of said incubating step is between about 35°C and about 60°C.

29 (Original). The method of claim 27, further comprising incorporating a glycolipid into the exterior surface of said HBsAg particle.

30 (Currently amended). The method of claim 29, wherein said incorporating step comprises co-incubating said glycolipid with said HBsAg particles and said biologically active molecule.

31 (Currently amended). In a method of generating a CTL response to an antigenic molecule in a mammalian subject, comprising administering by injection into the body of said subject an effective amount of a composition which comprises an antigenic molecule, the improvement whereby the CTL response is enhanced, wherein said antigenic molecule is either entrapped within the interior of an HBsAg particle or exposed or present at the surface of an HBsAg particle, said antigenic molecule being not covalently modified or covalently attached to said HBsAg particle.

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32(New). The method of claim 1, wherein said biologically active molecule is antigenic.

33(New). The method of claim 1, wherein said injection is selected from the group consisting of intraperitoneal, subcutaneous, intravenous, and intramuscular injection.

34(New). The method of claim 11, wherein said injection is selected from the group consisting of intraperitoneal, subcutaneous, intravenous, and intramuscular injection.

35(New). The composition of claim 17, wherein said biologically active molecule is antigenic.